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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,505	02/18/2004	Rafail Zubok	532-3X6	2913

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WESTFIELD, NJ 07090

EXAMINER
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CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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09/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/781,505

Applicant(s)

ZUBOK ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 and 06 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10-12, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Beaurain et al. (US Pub 2004/0243240 A1).

Beaurain et al. disclose a drill assembly comprising: an intervertebral disc replacement device (Fig. 2) including first (Fig. 2, ref. 3) and second members (Fig. 2, ref. 1) for insertion into an intervertebral disc space of a spinal column; an insertion plate (Fig. 14, ref. 953) for maintaining the first and second members in registration with one another (Fig. 14); and a drill guide (Fig. 13, ref. 93) including: a shaft (Fig. 13, shaft along axis of ref. d9) having a proximal end (Fig. 4, end near ref. 931) and a distal end (Fig. 13, end near ref. 934); and a guide member (Fig. 13, ref. 934) disposed at the distal end of the shaft (Fig. 13) and operable to engage the insertion plate (Fig. 14), wherein the guide member includes at least one guide bore (Fig. 13, e.g. ref. 935) operable to align with an area of a vertebral bone of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached. The guide member includes a first alignment element (Fig. 13, ref.

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934) operable to engage a second alignment element (Fig. 14, ref. 953) of the insertion plate and to enable a target orientation of a longitudinal axis of the guide bore relative to at least one of the vertebral bone and the one of the first and second members of the intervertebral disc replacement device. One of the first alignment element of the guide member and the second alignment element of the insertion plate includes an alignment stem (Fig. 14, ref. 953) and the other of the first alignment element and the second alignment element includes an alignment bore (Fig. 13, ref. 936, near ref. 934) the alignment stem being receivable within the alignment bore to enable the target orientation of the longitudinal axis of the guide bore (Fig. 14). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, top surface of ref. 3). The guide member includes a posteriorly directed surface (Fig. 14, ref. 934) and a spaced apart anterior directed surface (Fig. 13, top surface of ref. 93); the first alignment element of the guide member includes the alignment bore (Fig. 13, ref. 936, near ref. 934) extending from the posteriorly directed surface at least partially through the guide member toward the anteriorly directed surface (Fig. 13); and the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction (Fig. 14). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 13). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, top surface of ref. 3).

Beaurain et al. disclose an intervertebral disc replacement device (Fig. 2) including first (Fig. 2, ref. 3) and second members for insertion into an intervertebral disc

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space of a spinal column; an insertion plate (Fig. 14, ref. 953) for maintaining the first and second members in registration with one another (Fig. 14); and a drill guide (Fig. 13, ref. 93) including: a shaft (Fig. 13, shaft along axis of ref. d9) having a proximal end (Fig. 4, end near ref. 931) and a distal end (Fig. 13, end near ref. 934); and a guide member (Fig. 13, ref. 934) disposed at the distal end of the shaft (Fig. 13) and including at least one guide bore (Fig. 13, e.g. ref. 935), the guide member being operable to engage the insertion plate (Fig. 14), wherein the guide member is operable to achieve at least first and second alignment modes with respect to the insertion plate (Fig. 14), in the first alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with an area of a first vertebral bone of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached, and in the second alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with an area of a second vertebral bone of the intervertebral disc space to which the other of the first and second members of the intervertebral disc replacement device is to be attached (Fig. 14). The guide member includes a first alignment element (Fig. 13, ref. 934) operable to variably engage a second alignment element of the insertion plate to achieve the first and second alignment modes; in the first alignment mode, the first alignment element of the guide member is operable to engage the second alignment element of the insertion plate to enable a first target orientation of a longitudinal axis of the guide bore relative to at least one of the first vertebral bone and the first member of the intervertebral disc replacement device; and

in the second alignment mode, the first alignment element of the guide member is operable to engage the second alignment element of the insertion plate to enable a second target orientation of the longitudinal axis of the guide bore relative to at least one of the second vertebral bone and the second member of the intervertebral disc replacement device (Fig. 14). One of the first alignment element of the guide member and the second alignment element of the insertion plate includes an alignment stem (Fig. 14, ref. 953) and the other of the first alignment element and the second alignment element includes an alignment bore (Fig. 13, ref. 936, near ref. 934), the alignment stem being receivable within the alignment bore to enable rotational adjustment of the guide member relative to the insertion plate and to achieve the first and second alignment modes, since if only the very tip of the alignment stem is placed within the alignment bore rotational adjustment would be possible (Fig. 14). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, top surface of ref. 3); the second member of the intervertebral disc replacement device includes a second vertebral contact surface (Fig. 2, bottom surface of ref. 1). The guide member includes a posteriorly directed surface (Fig. 14, ref. 934) and a spaced apart anterior directed surface (Fig. 13, top surface of ref. 93); the first alignment element of the guide member includes the alignment bore (Fig. 13, ref. 936, near ref. 934) extending from the posteriorly directed surface at least partially through the guide member toward the anteriorly directed surface (Fig. 13); and the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction (Fig. 14) for engagement with the alignment bore (Fig. 14). The alignment bore

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has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 13). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, top surface of ref. 3); the second member of the intervertebral disc replacement device includes a second vertebral contact surface (Fig. 2, bottom surface of ref. 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, 13, 14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beaurain et al. (US Pub 2004/0243240 A1) in view of Michelson (US Pub. 2007/0106388 A1).

Beaurain et al. disclose the claimed invention except for a first flange including at least one through hole for receiving a bone screw for fastening the first member to the vertebral bone of the spinal column; and the guide member of the drill guide further includes a third alignment element operable to engage the at least one through hole of the first flange when the alignment stem is received within the alignment bore to further enable the target orientation of the longitudinal axis of the guide bore. The guide bore is disposed at least partially through the third alignment element such that the target orientation of the longitudinal axis of the guide bore is directed through the at least one

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through hole; a first flange including at least two through holes for receiving respective bone screws for fastening the first member to the vertebral bone of the spinal column; and the guide member of the drill guide further includes at least third and fourth alignment elements extending transversely from the posteriorly directed surface of the guide member and each being operable to engage a respective one of the through holes of the first flange when the alignment stem is received within the alignment bore to further enable the target orientation of the longitudinal axis of the guide bore. The guide member includes at least two guide bores, each being disposed at least partially through respective ones of the third and fourth alignment elements such that respective target orientations of longitudinal axes of the guide bores are directed through respective ones of the through holes. A second flange including at least one through hole for receiving a bone screw for fastening the second member to the second vertebral bone of the spinal column; and the guide member of the drill guide further includes at least a third alignment element operable to: (i) engage the at least one through hole of the first flange when the alignment stem is received within the alignment bore in the first alignment mode to further enable the first target orientation of the longitudinal axis of the guide bore, and (ii) engage the at least one through hole of the second flange when the alignment stem is received within the alignment bore in the second alignment mode to further enable the second target orientation of the longitudinal axis of the guide bore. The guide bore is disposed at least partially through the third alignment element such that the target orientations of the longitudinal axis of the guide bore may be directed through the respective through holes in the first and



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second alignment modes. A first flange including at least two through holes for receiving respective bone screws for fastening the first member to the first vertebral bone of the spinal column. A second flange including at least two through holes for receiving respective bone screws for fastening the second member to the second vertebral bone of the spinal column; and the guide member of the drill guide further includes at least a third and fourth alignment elements each operable to: (i) engage a respective one of the through holes of the first flange when the alignment stem is received within the alignment bore in the first alignment mode, and (ii) engage a respective one of the through holes of the second flange when the alignment stem is received within the alignment bore in the second alignment mode. The guide member includes at least two guide bores, each being disposed at least partially through respective ones of the third and fourth alignment elements such that in the first alignment mode, first and second longitudinal axes of the guide bores are directed through respective ones of the through holes of the first flange of the first member of the intervertebral disc replacement device in the second alignment mode, first and second longitudinal axes of the guide bores are directed through respective ones of the through holes of the second flange of the second member of the intervertebral disc replacement device.

Gill et al. disclose an assembly comprising an intervertebral disc replacement device (Fig. 1) including first (Fig. 1, ref. 40) and second members (Fig. 1, ref. 62) for insertion into an intervertebral disc space of a spinal column, the first and second members comprising flanges (Fig. 1, portion near ref. 34 and portion near ref. 56) which further comprise through holes (Fig. 1, ref. 36); the assembly further comprises a drill

guide (Fig. 13, ref. 70) that comprises a shaft having a proximal end and a distal end (Fig. 13); and a guide member (Fig. 13, ref. 76) disposed at the distal end of the shaft and operable to engage a complementary device (Fig. 17), wherein the guide member includes at least one guide bore (Fig. 13, ref. 82) operable to align with an area of a vertebral bone of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached. The guide bores can be considered to be at least partially disposed through the alignment elements, since the alignment elements can further be considered to be the portions of the device that extend from ref. 82 to the portions of the device that directly surround the bores. The drill guide further comprises alignment elements (Fig. 13, ref. 82) which are capable of engaging through holes of the flanges. This type of drill guide assembly allows the user to engage a complimentary device with the drill guide (Fig. 17) and allows screws to be placed through the apertures of the drill guide in order to fix the first and second members of the disc replacement device to their respective vertebrae without also fixing the drill guide to the vertebrae (paragraph 0045).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have utilized the drill guide, flanges, through holes, and bores as taught by Gill et al. with the assembly of Beaurain et al. in order to allow the user to engage a complementary device with the drill guide (Fig. 17) and allow screws to be placed through the apertures of the drill guide in order to fix the first and second members of the disc replacement device to their respective vertebrae without also fixing the drill guide to the vertebrae (paragraph 0045).

### ***Response to Arguments***

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

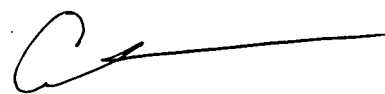
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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